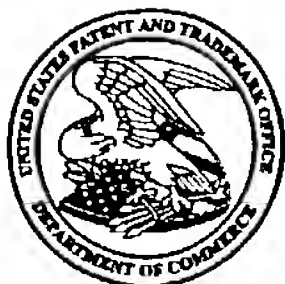


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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,874	08/22/2003	Timothy J. Miller	15463ZYXWV (PC9003E)	6784
23389	7590	06/16/2004	EXAMINER	
SCULLY SCOTT MURPHY & PRESSER, PC 400 GARDEN CITY PLAZA GARDEN CITY, NY 11530			HILL, MYRON G	
			ART UNIT	PAPER NUMBER
			1648	
DATE MAILED: 06/16/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/646,874

**Applicant(s)**

MILLER ET AL.

**Examiner**

Myron G. Hill

**Art Unit**

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1- 4, 6- 10, 13, 23, 28, 29, 31, 36, 38, 44, 46, and 49- 56 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1- 4, 6- 10, 13, 23, 28, 29, 31, 36, 38, 44, 46, and 49- 56 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1- 4, and 6- 10, drawn to a protein, classified in class 530, subclass 300.

If applicant elects group I, then they must elect-

- A) one from- a) diagnosis, b) treatment, or c) prophylaxis,  
B) one sequence for examination. This includes a SEQ ID# from claim 8 or the SEQ ID# and protein segment from claims 6 and 7.  
C) elect one virus from claims 2- 4.

Claims 36 and 38 will be examined with group I if prophylaxis is elected.

Claim 46 will be examined with group I if treatment is elected, and

- II. Claims 13, 31 drawn to a nucleic acid, classified in class 536, subclass 23.72.

If applicant elects group II, then they must elect-

- A) one from- a) diagnosis, b) treatment, or c) prophylaxis,  
B) one sequence for examination. This includes a SEQ ID# from claim 8 or the SEQ ID# and protein segment from claims 6 and 7, and  
C) elect one virus from claims 2- 4.

- III. Claims 23, 28, and 29, drawn to a method for recombinant production of a protein, classified in class 435, subclass 69.1.

If applicant elects this group they must elect as required for group II.

IV. Claim 44, drawn to a method of vaccinating, classified in class 424, subclass 187.1.

If applicant elects this group they must elect as required for group I.

V. Claim 49, drawn to a method of distinguishing one coronavirus from another using a protein, classified in class 435, subclass 5.

If applicant elects this group they must elect as required for group I.

VI. Claim 49, drawn to a method of distinguishing one coronavirus from another using a primer, classified in class 435, subclass 5.

If applicant elects this group they must elect a sequence from Table II (SEQ ID#s 1- 18).

VII. Claim 49, drawn to a method of distinguishing one coronavirus from another using a nucleic acid, classified in class 435, subclass 5.

If applicant elects this group they must elect as required for group II.

VIII. Claims 49 and 50, drawn to a method of distinguishing one coronavirus from another using an antibody, classified in class 435, subclass 5.

If applicant elects this group they must elect a protein from group I to indicate binding specificity.

IX. Claims 51 and 54, drawn to a peptide, classified in class 530, subclass 300.

If applicant elects this group, then applicant must elect a segment and SEQ ID# that contains the segment or a SEQ ID# that represents the segment.

X. Claims 52 and 54, drawn to a peptide, classified in class 530, subclass 300.

If applicant elects this group, then applicant must elect a SEQ ID# ((a) to (i)) or the size that corresponds to ((a) to (i)) in (j).

XI. Claim 53, drawn to a DNA sequence, classified in class 536, subclass 23.72.

If applicant elects this group, then applicant must elect one SEQ ID# as required in Group IX or X.

XII. Claim 55, drawn to an antibody, classified in class 530, subclass 387.1.

If applicant elects this group, then applicant must elect one SEQ ID# as required in Group IX or X to determine the binding specificity.

XIII. Claim 56, drawn to a method for distinguishing one coronavirus from another using a peptide, classified in class 435, subclass 5.

If applicant elects this group, then applicant must elect a SEQ ID# as required in Group IX or X.

XIV. Claim 56, drawn to a method for distinguishing one coronavirus from another using a DNA sequence, classified in class 435, subclass 5.

If applicant elects this group, then applicant must elect one SEQ ID# as required in Group IX or X.

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XV. Claim 56, drawn to a method for distinguishing one coronavirus from another using an antibody, classified in class 435, subclass 5.

If applicant elects this group, then applicant must elect one SEQ ID# as required in Group IX or X.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, and IX- XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to different structures (protein, nucleic acid or antibody). Each protein, nucleic acid, and antibody are different from others of the same kind because they encode different sequences, are proteins with different sequences or are antibodies that bind to different structures.

Inventions I, II, and IX- XII (products) and III- VIII and XIII- XV (methods) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the methods can be practiced with the different proteins or nucleic acids as claimed.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, different searches for each sequence and for different methods and uses, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.




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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Myron G. Hill  
Patent Examiner  
8 June 2004

  
JAMES HOUSEL 6/14/04  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600